

TABLE 5

(A) Concentrating the 59% peroxide solution			
Ratio of peroxide to water			
	Before concentrating	Right after concentrating	After all peroxide vaporized
Solution in vaporizer	1.4:1	19:1	none
Vapor in chamber	<1.4:1	0.85:1	4.9:1

TABLE 4

(A) Effect of water to peroxide ratio on efficacy			
Sterility results (positives/samples)			
Lumen Dimension (Diameter) × (length)	Without concentrating process	With concentrating process	
	8.43 mg/L H <sub>2</sub> O 12 mg/L H <sub>2</sub> O <sub>2</sub>	1.49 mg/L H <sub>2</sub> O 7.3 mg/L H <sub>2</sub> O <sub>2</sub>	
1 × 400 mm	2/2	0/2	
1 × 350 mm	2/2	0/2	
1 × 300 mm	2/2	0/2	
1 × 250 mm	2/2	0/2	

The process may be further enhanced by admitting sufficient hydrogen peroxide into the system so as to force some of the vaporized solution to condense upon the instruments being sterilized within the system. As described above, the solution can be vaporized by admitting it into the system at any pressure above the vapor pressures of water and hydrogen peroxide in the solution and then vaporized by reducing the pressure, or by admitting the solution at a pressure substantially below these vapor pressures whereupon it will start to vaporize thus releasing gas and increasing the pressure. In the second scenario if the pressure is then further reduced by pumping the concentration of the hydrogen peroxide in the system can be increased. This is especially true if the pressure rises to a level at least above the vapor pressure of hydrogen peroxide thereby limiting further vaporization of hydrogen peroxide from solution and perhaps encouraging some of the hydrogen peroxide to condense upon objects such as instruments within the system. Some of the water vapor would likely also condense in such event. By controlling the pressure excess water vapor would be exhausted from the system and then the condensed solution would re-vaporize. To the extent that such solution had condensed within diffusion restricted areas the re-vaporization therein would further increase the concentration in the those areas to enhance the sterilization efficacy therein. The quantity of solution admitted will primarily determine the pressure rise to initiate such condensation. The process is described in more detail in our co-pending application entitled "Sterilization of Diffusion-Restricted Area by Re-Vaporizing the Condensed Vapor" filed contemporaneously herewith.

A typical cycle might comprise placing a load of instruments (not shown) within a CSR wrapped tray within the chamber 30 and then drawing a vacuum on the chamber 30 with the pump 32 down to below 1 torr or about 0.4 torr. An electromagnetic field applied to the chamber 30 at such time tends to drive any remaining water into the vapor or plasma stage so that it can be removed by the pump 32. The pump 32 can be cycled or merely run continuously with the valve 34 controlling the vacuum process. Fresh dry air may be

admitted to the chamber 30 including raising of the pressure back to atmosphere. Preferably the hydrogen peroxide solution, preferably a 59% hydrogen peroxide solution, is admitted to the vaporizer 36 at atmospheric pressure and then the pump 32 exhausts the chamber 30 to a level at which the solution begins to vaporize. A monitor 100 for hydrogen peroxide vapor and monitor 102 (see FIG. 6) for water vapor in connection with an automated control system 104 can be employed to optimize the pressure conditions to enhance the initial vaporization and exhaust of water vapor. After the solution is sufficiently concentrated the pressure in the chamber 30 can be further lowered to vaporize the remaining solution. The valve 32 is closed to isolate the chamber 30 and the vaporized hydrogen peroxide solution is allowed to diffuse throughout the chamber to contact the instruments. Additional dry air or other gas can be admitted at this time to help push the sterilizing vapors into diffusion restricted areas, with the chamber 30 then further exhausted to resume a vacuum in the range of 2 to 10 torr. Additional admissions of air and vacuum can be employed, especially in connection with additional admission and concentration of hydrogen peroxide solutions. After the hydrogen peroxide vapors have diffused throughout the chamber for a sufficient time an electromagnetic field may be applied to drive the vapor into the plasma stage and effect further sterilization. When the field is removed the ions formed from the hydrogen peroxide recombine as water and oxygen, leaving little residual hydrogen peroxide. The chamber can be raised to atmospheric pressure and the load removed.

It should be noted that the present invention is not limited to only those embodiments described in the Detailed Description. Any embodiment which retains the spirit of the present invention should be considered to be within its scope. However, the invention is only limited by the scope of the following claims.

What is claimed is:

1. A method of furnishing concentrated hydrogen peroxide vapor to an article comprising the steps of:

placing the article into a chamber containing an inner atmosphere;

placing a solution comprising hydrogen peroxide and water into fluid communication with the chamber, said solution having a ratio of hydrogen peroxide to water; vaporizing the solution in the inner atmosphere to form water vapor and hydrogen peroxide vapor;

selectively drawing water vapor from the chamber to increase a ratio of hydrogen peroxide to water in the chamber;

contacting the article with the hydrogen peroxide vapor; and

wherein the step of contacting the article with the hydrogen peroxide vapor is limited

to less than one hour and achieves a level of sterilization such that in a straight round lumen having two open ends, a diameter of 1 mm and a length of 250 mm with 10<sup>6</sup> viable spores of *B. Stearothermophilus* located within the lumen at a midpoint thereof, all of the spores would be killed.

2. A method according to claim 1 wherein the ratio of hydrogen peroxide vapor to water vapor after the step of selectively drawing water vapor from the chamber exceeds the ratio of hydrogen peroxide to water in said solution.

3. A method according to claim 1 wherein the ratio of hydrogen peroxide to water, by weight, after the step of selectively drawing water vapor from the chamber exceeds 3 to 1.

different

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4. A method according to claim 3 wherein the ratio of hydrogen peroxide to water in said solution, by weight, is less than 3 to 1.

5. A method according to claim 3 wherein the ratio of hydrogen peroxide to water in said solution, by weight, is less than 3.2

6. A method according to claim 3 wherein the ratio of hydrogen peroxide to water, by weight, after the step of selectively drawing water vapor from the chamber exceeds 4 to 1.

7. A method according to claim 1 wherein the step of selectively drawing water vapor from the chamber comprises placing said solution within a diffusion restricted environment in fluid communication with the chamber during the step of vaporizing the solution.

8. A method according to claim 7 wherein the diffusion restricted environment is more diffusion restricted during the step of selectively drawing water vapor from the chamber than during a portion of the step of vaporizing the solution during which the hydrogen peroxide is vaporizing at a faster rate than the water.

9. A method according to claim 7 wherein the water vapor is drawn from the chamber through one or more exhaust ports and wherein the one or more exhaust ports are physically remote from the diffusion restriction.

10. A method according to claim 1 wherein the step of selectively drawing water vapor from the chamber comprises the steps of controlling the temperature and pressure of the solution during the step of vaporizing the solution to enhance vaporization of the water from solution versus vaporization of hydrogen peroxide and extracting at least a portion of the water vapor from the chamber.

11. A method according to claim 10 wherein the temperature of the atmosphere in the chamber is above room temperature and the temperature of the solution during the vaporizing step is at least 10° C. below the temperature of the atmosphere in the chamber.

12. A method according to claim 1 wherein the step of selectively drawing water vapor from the chamber comprises the steps of maintaining the solution at a pressure below the vapor pressure of the water in the solution and above the vapor pressure of the hydrogen peroxide in the solution.

13. A method according to claim 1 wherein the solution is vaporized by pumping a portion of the atmosphere out of the chamber to lower the pressure of the chamber at a rate

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selected to control removal of the water and hydrogen peroxide from the solution so as to concentrate the hydrogen peroxide remaining in the chamber.

14. A method according to claim 1 wherein the temperature of the solution during the vaporizing step is held below the temperature of the atmosphere in the chamber whereby to increase the vapor pressure of the water in the solution relative to the hydrogen peroxide in the solution whereby to enhance vaporization of the water from the solution in preference to vaporizing the hydrogen peroxide from the solution.

15. A method according to claim 13 wherein the solution is vaporized in a vaporizer which is in fluid communication with the chamber and wherein the vaporizer is thermally isolated from the chamber.

16. A method according to claim 1 and further comprising the steps of controlling the temperature and pressure of the solution during a least a first portion of the vaporizing step so as to selectively vaporize water from the solution and concentrate hydrogen peroxide therein to form a concentrated solution and during a second portion of the vaporizing step raising the temperature of the concentrated solution and vaporizing the concentrated solution.

17. A method according to claim 1 and further comprising the steps of controlling the temperature and pressure of the solution during a least a first portion of the vaporizing step so as to selectively vaporize water from the solution and concentrate hydrogen peroxide therein to form a concentrated solution and during a second portion of the vaporizing step not withdrawing atmosphere from the chamber.

18. A method according to claim 1 and further comprising the step of drying the chamber prior to the step of vaporizing the solution.

19. A method according to claim 18 wherein the step of drying the chamber comprises pumping a portion of the atmosphere out of the chamber.

20. A method according to claim 18 wherein the step of drying the chamber comprises applying energy to excite molecules of liquid water within the chamber into the gaseous or plasma state of matter and pumping a portion of the atmosphere out of the chamber.

21. A method according to claim 1 wherein the solution comprises peracetic acid.

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